K140322

JUN 12 2014

510 (K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21CFR 807.92.

1. **Submitter's Identification:**

Shandong Dawei Medical Products Co., Ltd.
No.50, Yongzhou Road
Nanshan Industrial Park,
Qingzhou, Shandong, 262500
China

Date summary prepared: June 4, 2014

2. **Name of the Device:**

White Vinyl Exam Gloves Powder Free

3. **Common name/classification name of the Device:**

White Vinyl Exam Gloves Powder Free

4. **Trade Name**

White Vinyl Exam Gloves Powder Free

5. **Contact Person:**

Sophie Hao, Tel: 909-548-4828
Email: sophie.hxf1989@gmail.com

6. **Predicate Device Information:**

Shijiazhuang Hongxiang Plastic Products Ltd.
Synthetic Vinyl Patient Examination Gloves – Powder Free (K992821)

7. **Device Description:**

Device Class: Class I
Regulation number: 21 CFR 880.6250
Product code: LYZ
White Vinyl Exam Gloves Powder Free is a disposable device intended for medical purposes that is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner. Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 880.6250, Powder-Free

Vinyl Patient Examination Glove. 80LYZ. and meets all requirement of ASTM Standard D5250-06.

8. **Intended Use:**

A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner.

9. **Comparison to Predicate Devices:**

Shandong Dawei Medical Products Co., Ltd. White Vinyl Exam Gloves Powder Free are substantially equivalent in safety and effectiveness to the Shijiazhuang Hongxiang Plastic Products Co., Ltd. (K992821)

10. **Discussion of Non-Clinical tests performed for Determination of Substantial Equivalence are as follows:**

The standards used for Shandong Dawei Medical Products Co., Ltd. glove production are based on ASTM-D-5250-06. All testing meets requirements for Physical and Dimensions Testing conducted on gloves, Inspection Level S-2, AQL 2.5.

The FDA 1000 ml. Water Fill Test was also conducted with samplings of AQL 2.5, Inspection Level I, meeting these requirements. Primary Skin irritation and Skin Sensitization (allergic contact dermatitis) testing was conducted with results showing no primary skin irritant or sensitization reactions.

There are no special labeling claims and we do not claim our gloves as hypoallergenic is conducted to insure that our gloves meet our "powder-free" claims (contain no more than 2 mg powder per glove).

11. **Discussion of Clinical Tests Performed:**

Not Applicable – There is no hypoallergenic claim.

12. **Conclusions:**

The conclusion draws from the nonclinical and clinical test that demonstrate that the as safe, as effective, and performs as well as, or better than the legally market predicate device Shijiazhuang Hongxiang Plastic Products Co., Ltd. Powder-free Vinyl Patient Examination Gloves (K992821). Our White Vinyl Exam Gloves Powder Free conform fully to ASTM-D-5250-06 standard as well as applicable 21 CFR references, and, meets pinhole FDA requirements, biocompatibility requirements and labeling claims.

Table 7-2. Side-by-Side Comparison of Intended Use, Design, Material, Physical, Biocompatibility, and Performance Testing

	Proposed Device	Predicate Device (K992821)
Description	Shandong Dawei Medical Products Co., Ltd. White Vinyl Exam Gloves Powder Free	Shijiazhuang Hongxiang Powder-free Vinyl Patient Examination Gloves
Labeling: Instruction for use	A garment covering the hand and wrist area. Clovers have separate openings for each finger and the thumb.	A garment covering the hand and wrist area. Clovers have separate openings for each finger and the thumb. Substantially equivalent
Labeling: Labels on the carton	Labels include: Product name; color; "single use Only" size, piece count, lot number, distributor name, and manufacturer address.	Labels include: Product name; "single use Only" size, piece count, distributor name, and manufacturer address. Substantially equivalent
Indication For Use	A disposable device intended for medical purposes that is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner.	A disposable device intended for medical purposes that is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner. Substantially equivalent
Device Materials	Poly Vinyl Chloride Polyurethane Diisononyl Phthalate (DINP)	Poly Vinyl Chloride Polyurethane Diisononyl Phthalate (DINP)
Before Aging: Tensile Strength(Mpa) and Ultimate Elongations	Average Tensile Strength (Mpa): 16.84 Average Ultimate Elongations: 520%	Average Tensile Strength (Mpa): 16.80 Average Ultimate Elongations: 510% Substantially equivalent
After Aging: Tensile Strength(Mpa) and Ultimate Elongations	Average Tensile Strength (Mpa): 14.96 Average Ultimate Elongations: 481%	Average Tensile Strength (Mpa): 15 Average Ultimate Elongations: 480% Substantially equivalent
Overall Length on Medium Size	Average over 232.23mm	Average over 232mm Substantially equivalent
Width of Palm on Medium Size	Average 95mm	Average 96 mm Substantially equivalent
Palm Thickness	Average 0.095 mm	Average 0.096 mm Substantially equivalent
Figure Thickness	Average 0.090 mm	Average 0.091 mm Substantially equivalent

Residual Powder	According to ASTM D6124-06 Standard Test Method for Residual Powder on Medical gloves for the determination of residual powder content. Testing result indicates the weight of all types of residual or powder on finished powder-free gloves as < 2 mg per glove and there is no defect glove found according to ASTM D6124-06.	According to ASTM D6124-06 the weight of all types of residual or powder on finished powder-free gloves as < 2 mg per glove and there is no defect glove found according to ASTM D6124-06. Substantially equivalent
Pinhole Results	According to ASTM D5151-06. Testing result indicates pinhole were found less than two pieces gloves out of 125 pieces gloves. AQL 2.5 is met.	According to ASTM D5151-06. testing result indicates pinhole were found less than two pieces gloves out of 125 pieces gloves. AQL 2.5 is met. Substantially equivalent
Biocompatibility Result: Primary Skin Irritation	Under the condition of the study, the device is not an irritant	not an irritant. Substantially equivalent
Dermal Sensitization	Under the condition of the study, the device is not a sensitizer	not a sensitizer Substantially equivalent
Summary of comparison	Shandong Dawei Medical Products Co., Ltd. White Vinyl Exam Gloves Powder Free (subject device) and Shijiazhuang Hongxiang Powder-free Vinyl Patient Examination Gloves (predicate device) are substantially equivalent in all technological characteristics, including tensile strength, ultimate elongations size, thickness, residual powder and pinhole.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 12, 2014

Shandong Dawei Medical Products Company, Limited
C/O Ms. Sophie Hao
Official Correspondent
Basic Medical Industries Incorporated
12390 East End Avenue
Chino, CA 91710

Re: K140322
Trade/Device Name: White Vinyl Exam Gloves Powder Free
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: May 5, 2014
Received: May 8, 2014

Dear Ms. Hao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140322

Device Name
White Vinyl Exam Gloves Powder Free

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☑ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sreekanth Gutala -S

Digitally signed by Sreekanth Gutala -S
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